1,153,622

PATENT SPECIFICATION

DRAWINGS ATTACHED

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COMPLETE SPECIFICATION

Medical Probe System

We, HARRY ZEIMER AND ARIEL SIMKIN, both Israel citizens of Kiryat Moshe, Beth Bension 2, Jerusalem, Israel and Bayit VeGan Street, 37, Bayit VeGan, Jerusalem, Israel and the State of Israel, Jerusalem, Israel, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to medical probe systems which are extendible into a body cavity or tract and which can be subsequently retracted therefrom.

Known probes of this kind suffer from the disadvantage that the introduction thereof into the body cavities or tracts is accompanied by friction along the walls of the cavity causing discomfort and pain and even injury to the tissues.

The present invention seeks to provide a medical probe system in which the disadvantages referred to above are substantially overcome or reduced.

According to the present invention there is provided a medical probe system comprising in combination a fluid distribution body constituting a probe holder, open at leaast at one end and provided with inlet and outlet ducts, a probe cartridge sealingly receivable in and removable from said holder and including an elongated flexible tube anchored at its ends with respect to the holder and means for supplying fluid under pressure through said fluid inlet duct to said probe cartridge so as to pressurize said tube and cause it to extrovert and to extend out of said end, or out of one of said ends.

As used in the present specification and claims the term "extroversion" (and terms grammatically related thereto) refers to the turning inside out of a flexible length of tubing. As a result of extroversion the inner wall of the tubing is continuously converted into the outer wall of the probe which increases in length and can be extended into the body cavity or tract substantially avoiding sliding friction and the pain and damage consequent thereof.

Normally, probes in accordance with the invention would require preparation, assembly and cleaning after use. This would require the expenditure of considerable time and skill especially where the probes have the form of relatively long, inwardly folded tubes of film-like material frequently made of regenerated cellulose, collagen or the like. Unskilled handling of the probe could lead to tearing of the probe and/or the formation of kinks or other obstructions especially when it is a question of introduction into body tracts or cavities which are at least 70 cms in length.

Particularly when the probes are designed for gastro-enterological use and, in view of the difficulties of cleaning after use, it is desirable that the probes be disposable after a single use. Furthermore it is highly desirable that the preparation and assembly of the probe be rendered as simple as possible.

By the provision, in accordance with the present invention, of a medical probe system having readily insertable and removable probe cartridges, the medical requirements can be satisfied.

Various embodiments of medical probe systems and the component parts thereof in accordance with the present invention will now be described by way of example and with reference to the accompanying drawings in which:

Fig. 1 is a longitudinal sectional view of a probe cartridge for use with a fluid distributing body of a medical probe system in accordance with the present invention,

Figs. 2 and 3 are front and side elevations respectively of a first form of fluid distributing body,

Fig. 4 is a longitudinal sectional view of a second form of a fluid distributing body to which is fitted a probe cartridge,

Fig. 5 is a cross-sectional view of the body

[*Price 4s. 6d.*]

shown in Fig. 4 taken along two transverse sectional lines,

Figs. 6, 7 and 8 are longitudinal sectional views of three different kinds of probe cartridges for use with the device shown in Figs. 4 and 5,

Figs. 9 and 10 are side and front elevations of disassembled probe systems,

Fig. 11 is a sectional side elevation of a probe cartridge,

Fig. 12 shows the probe cartridge shown in Fig. 11 fitted in a probe system, and

Fig. 13 shows the modification of the nose of the cartridge shown in Fig. 11, or that of the probe dispenser shown in Figs. 11 and 12 to render them suitable for use with the distributor device shown in Figs. 4 and 5.

Reference will now be made to Fig. 1 of the drawings which illustrates in a schematic form a two-ended, flexible extended probe cartridge 1 for use in a medical probe system in accordance with the invention. The probe cartridge includes a tube 1 which is secured to the rims 3 and 4 of a tubular casing 2 having an inlet port 5, an annular chamber being defined between the casing 2 and the tube 1. The introduction of pressurized fluid into the annular chamber results in the inflation and extension of the probe. With such an extended probe made of a flexible but substantially inextensible material it will be realised that the volume of the annular chamber remains substantially constant. If now a cylindrical object is inserted into the central tubular cavity of the probe (the object being of slightly greater diameter than the central tubular cavity) the walls of the central tubular cavity will be pressed against the object and will move with it. In consequence if the object is introduced at the right-hand end of the probe shown in Fig. 1 this end will introvert whilst the left-hand end will extrovert and can be made to extend into a body cavity or tract, the movement continuing until the head of the cylindrical object emerges from the left-hand end of the probe. This cylindrical object can be constituted by an instrument which is to be introduced into the tract by the probe. The instrument such as a fiberscope or a biopsy tube can thus be introduced into the body cavity without frictional rubbing on the cavity wall. Where the purpose of introducing the instrument is to inspect visually or to record photographically the cavity, the probe can be made of a substantially transparent material in which case the instrument can "see" the cavity wall even before emerging from the advancing end of the probe.

Figs. 2 and 3 illustrate a specific form of probe holder for use with the type of probe cartridge just described. This device comprises a main body 7 with a throughgoing aperture 8 which is tapped at both ends so as to facilitate the connection of probe adapters 8*a* (only one being shown in Fig. 3) of varying diameters, to either end of the body 7 to which adapters the ends of the flexible probe (not shown) are to be secured, the flexible probe and the probe adapters together constituting a probe cartridge. The body 7 is furthermore formed with a pair of ducts 9 and 10 the inner ends of which communicate with the interior of the aperture 8 and the outer ends of which communicate with inlet and outlet ports 11 and 12 which can, if desired, be coupled via flexible tubing, etc., to inlet and outlet valves 13 and 14, the inlet valve 13 being coupled to a fluid supply source, whilst the outlet valve 14 is coupled to a sink or to the outer atmosphere. The body 7 is formed integrally with a supporting limb 15 which is slidable (for height adjustment) on a support rod 16 and can be fixed in position with respect to the support rod 16 by means of a clamping screw 17. The support rod 16 terminates in a ball 16a located in a socket 16b of a base member 16c. A clamping screw 16d is provided allowing for the rod 16 to be clamped in any desired direction.

The body 7 is provided with a further duct 18 communicating with the interior of the aperture 8 and which communicates with an auxiliary inlet port 19 adapted to be sealed by a screw cap 20. Communication between the inlet valve 13 and the inlet port 11 can be by way of a pressure gauge.

The probe adapters 8*a* to be screwed into the tapped apertures 8 each comprise an externally threaded skirt 8*b* formed integrally with an apertured disc 8*c* and with a tubular extension 8*d*. Adapters having tubular extensions of differing diameters can be employed to accommodate probes of differing diameters.

In use, a flexible probe (not shown) is threaded through the central aperture 8 in the body 7 and both ends of this probe are secured to the tubular extensions 8*d* of the probe adapters 8*a* which have been previously fixed in position on either side of the central aperture 8 of the body 7. The ends can be secured to these extensions 8*d* of rubber rings 8*e*. The fluid is then introduced into the closed envelope of the probe via the inlet valve 13 and inlet port 11, the outlet port 12 and valve 14 being maintained open until all air has been expelled. With the expulsion of air the outlet valve 14 is closed and the fluid pressure in the probe is raised until the probe is fully expanded and extended, generally to one side of the probe holder. If now it is desired to insert the other end of the probe into for example, a body cavity a cylindrical object is inserted into the central core of the extended probe and thereby cause the extroversion of the other end into the cavity.

The auxiliary inlet 19 in the distributor body can be used to introduce into the probe an auxiliary fluid, for example an X-ray contrast fluid. When not in use, this auxiliary inlet 19 is sealed by means of the screw cap 20.

A modified arrangement of a probe cartridge and a fluid distributor is illustrated in Figs. 4 and 5 of the drawings. As can be seen from Fig. 4 the probe cartridge is constituted by a flexible tube 21, preferably disposable, whose ends are secured to a tubular casing 22. This casing 22 is provided with a set of circumferential apertures 23 by means of which communication may be made with the inside of the probe. The associated probe fluid distributor and holder device 24 comprises a main body 25 having a throughgoing aperture 26 and is supported on a support rod 27. Set into the aperture wall of the distributor body 25 and spaced axially apart are three sealing rings 28, 29 and 30 respectively engaging the inner wall of the main body 25 and the outer wall of the casing 22. Formed in the distributor body 25 is an inlet duct 31 communicating at one end with an inlet port 32 and at the other end with the main aperture 26 and an outlet duct 33 communicating at one end with an outlet port 34 and at the other end with an auxiliary cross-duct 35 which in its turn communicates with the main aperture 26, and with the atmosphere. The auxiliary duct 35 is adapted to be sealed when not in use by a screw cap 36. A spring loaded locating pin 37 is located in the distributor body 25, the tip 38 of the pin 37 projecting downwardly out of the body 25 into the throughgoing aperture 26. A spring 39 presses the locating pin 37 downwardly but the pin 37 can be raised against its spring biasing.

The casing 22 which is constructed for insertion into the throughgoing aperture 26 of the distributor body 25 is formed with an end portion 41 of reduced diameter bounded by a shoulder 42 which fits against the outer wall of the distributor body 25. The set of peripheral apertures 23 of the casing are arranged to communicate with the inlet duct 31 and to be located between the sealing rings 28 and 29 whilst a further set of peripheral apertures 43 is arranged to communicate with the outlet duct and to be located between the sealing rings 29 and 30. The casing 22 is furthermore provided, adjacent its shoulder, with a peripheral groove 44 in which is located the tip 38 of the locating pin 37.

In use a probe cartridge which can take any of the forms to be described below with reference to Figures 6—8, has its casing 22 inserted in the throughgoing aperture 26 of the distributor body 25 and when the tip 38 of the locating pin 37 engages the locating groove 44 of the casing 22 it is ensured that the various sets of apertures of the casing are correctly aligned with the corresponding ducts of the distributor body. The inlet port 32 of the distributor body is connected to a source of fluid supply whilst the outlet port 34 is connected to a sink or to the outer atmosphere, both these connections being suitably made through appropriate valves (not shown). When it is desired to operate the probe the procedure described above (with reference to Figs. 1 and 2) for filling the probe with the fluid under pressure is followed and as a result the probe extroverts and advances from one end of the distributor body in a desired direction and into any desired cavity or tract, the preferred direction of advance being determined by manually obstructing advance from the other end of the distributor body. The distribution body auxiliary duct 35 which can normally be sealed by the screw cap 36 can be used for the introduction of an auxiliary fluid, such as for example an X-ray contrast medium. The probe cartridge can be inserted into the distribution body in any angular position relative to its axis and by virtue of the fact that the inlet apertures are distributed around the periphery of the probe cartridge communication is readily effected between the various inlet and outlet ducts and the corresponding apertures in the probe.

Reference will now be made to Figs. 6, 7 and 8 which illustrate three alternative embodiments of disposable probe cartridges for use with a distributor probe holder as shown in Figs. 4 and 5 of the drawings. In each case the cartridge includes a rigid casing 22 described previously with reference to Fig. 4. As seen in Fig. 6 one end of the flexible tube 21 is secured by bonding to one rim of the casing 22, the tube extending through the casing 22 and being extroverted and packed in bellows fashion at its other end which is secured by bonding to the other end of the casing 22.

In the embodiment shown in Fig. 7 the ends of the flexible tube 21 are respectively secured by bonding to the ends of the casing and the tube itself is packed in bellows fashion inside the casing itself.

In the embodiment shown in Fig. 8 the ends of the flexible tube are again respectively secured by bonding to the ends of the casing but the tube itself is coiled into a compact form in the casing itself.

The probe cartridges just described, can be provided on the nose end thereof, i.e. the end to be inserted into the distributor body with a removable cap which is maintained in position when the probe is extended from the opposite end by the introduction of fluid under pressure. In this way it is ensured that the extension or developing of the probe takes place only in one direction, i.e. away from the nose. Then, when it is desired to introduce the extended probe with an instrument into a cavity the cap is removed, the instrument is inserted into the probe at the extended end thereof and the probe advances by extroversion from the nose.

Reference will now be made to Figs. 9 and 10 of the drawings which illustrate a probe dispenser unit for use with a coiled retractable probe. As seen in the drawings the unit com-

prises a rectangular box 51 which has an open base sealed by a rectangular cover member 52 constituted by a base plate 53 and an upwardly projecting rectangular boss 54 adapted to extend into the box, the upper surface of this rectangular boss 54 being provided with a sealing surface 55 adapted to press, sealingly, against corresponding shoulders formed in the side walls of the box. The lower surface of the base plate 53 is provided with two cavities 56 for a purpose to be described below. The cover member 52 is adapted to be locked to the box 51 by a channel-shaped locking member 57 whose vertical limbs 58 terminate in inwardly directed flanges 59 which form an acute angle with the vertical limbs 58. Corresponding slots 60 are formed in the transverse walls of the box 51 extending along the length of these walls and the locking member is adapted to be slid into locking position with its flanges 59 riding in these slots 60. When the locking member 57 is in the required position it can be securely locked by means of a pair of locking bolts 61 extending through the base of the locking member 57 into the cavities 56 in the closing member referred to above. When these bolts are tightened the cover member is pressed home thereby sealing the base of the box. A withdrawable square sectioned shaft 63 extends through the box and is journalled, at one end thereof, on conical bearings 64 mounted in the box and extends at the other end thereof into a suitable sealing box 65 from where it is coupled to a turning handle 66. An upper side wall of the box is provided with an outlet aperture 67 in which can be fitted probe adapters (such as those previously described with reference to Fig. 3) of different diameters. On the probe adapter is fitted an auxiliary inlet adapter 69 which is normally sealed by means of a screw 70 and which can also accommodate means for introducing an auxiliary fluid. Alternatively, the auxiliary inlet adapter 69 can be coupled to manually operated means such as a pressure balloon by means of which intermittent pressure variations can be achieved.

The probe to be dispensed is in the form of a long flexible tube (not shown) which is wound on a reel 71 mounted on the retractable shaft. In order to mount the reel 71 in position the box 51 is opened by removing the locking member 57 and the cover member 52 is removed and the shaft 63 is retracted. The reel 71 is mounted in position in the box after which the shaft 63 is pressed through the box 51 so that the reel 71 is pivotally mounted on the shaft 63. The box 51 is then closed as described above, the end of the probe is drawn off the reel through the outlet aperture 67 and is fixed on the probe adapter and inlet and outlet ports 51a and 51b of the box 51 are respectively coupled to a source of fluid pressure and to a sink or the outside atmosphere. The inlet port 51a and outlet port 51b are then opened whereupon the dispensing box becomes filled with the filling fluid and all air is expelled. After the air is expelled the outlet port 51b is sealed and the continued flow of fluid into the box 51 results in the dispensing of the probe through the outlet aperture and the extroversion thereof. When it is desired to retract the probe the inlet port 51a is closed and the outlet port 51b opened and the probe retracted by winding the handle thereby causing the retraction of the probe and the expulsion of the fluid.

Fig. 11 shows a form of probe cartridge which can be readily introduced into a probe dispenser substantially as described above with reference to Figs. 9 and 10. As before, the cartridge consists of a reel 72 upon which is wound the flexible tube 73. Articulated to the reel 72 and freely rotatable with respect to the reel 72 about the axis thereof is a connecting member 74 which consists basically of a tube having a curved under-portion 74a allowing it to slide rotatably with respect to the reel 72. The end of the flexible tube 73 passes through the connecting member and is secured to a nose end 75 of the connecting member 74. The nose end 75 merges via a flanged shoulder 76 with the rest of the member 74 and is provided with a locating aperture 77 and an inlet aperture 78.

In operation the cartridge is inserted into a dispenser box 151a as shown in Fig. 12 and a cover member 52a similar to the cover member 52 described with reference to Fig. 10 is pressed into position by bolts 61a and causes the nose 75 of the connecting member 74 to be pressed through an outlet aperture 67a of the box. The shoulders 76 of the connecting member 74 bearing via sealing gaskets 79 on corresponding shoulders 80 surrounding the outlet aperture 67a. In this way the cartridge is firmly sealed in position whereupon the square-sectioned shaft 63a similar to the shaft 63 described with reference to Fig. 10 is passed through a corresponding aperture formed in the reel. A locating screw 81 in the box is tightened the end of it projecting through the locating aperture 77 whilst an inlet 82 of the box is aligned with the inlet aperture 78 of the cartridge. As seen the dispensing box is provided with inlet and outlet ports 82 and 84. In operation, as before, when it is desired to dispense the probe both ports 82 and 84 are opened, the inlet port 82 having been connected to a source of fluid supply and the outlet port 84 having been connected to a sink. When the box 151a is full of fluid the outlet port is closed and the continued flow of fluid into the dispensing box 151a under pressure causes the dispensing of the probe. Retraction of the probe can then be effected by means of rotating the handle 66a as a result of which the fluid is expelled from the probe in the box via the outlet duct 84.

As seen in Fig. 13 of the drawings the pro-

jecting nose 75 of the cartridge can be suitably modified so as to render it suitable for use with a fluid distributor device as described with reference to Figs. 4 and 5. In this event the modified nose 75a of the cartridge is coupled to the fluid distributor device whilst the cartridge is inserted and mounted in a dispenser box which, in this case of course, has no inlet or outlet ports, the fluid flowing into and out of the probe via the holes in the nose of the cartridge.

WHAT WE CLAIM IS:—

1. A medical probe system comprising in combinationa fluid distribution body constituting a probe holder, open at leeast at one end and provided with inlet and outlet ducts, a probe cartridge sealingly receivable in and removable from said holder and including an elongated flexible tube anchored at its ends with respect to the holder and means for supplying fluid under pressure through said fluid inlet duct to said probe cartridge so as to pressurize said tube and cause it to extrovert and to extend out of said end, or out of one of said ends.

2. A combination according to claim 1 wherein said cartridge furthermore includes a rigid casing to which the ends of the tube are anchored and being open at least in the direction of said one end or ends and defining with said tube an annular chamber, at least one port being formed in said casing through which said fluid can be admitted into said chamber.

3. A combination according to claim 2, further comprising sealing means engageable with an inner wall of said holder and with the outer wall of said casing.

4. A combination according to claim 2 or 3 wherein said casing is formed along its outer surface with a recess, said holder being provided with a spring loaded inwardly biased pin receivable in said recess for positioning said cartridge in said holder.

5. A combination according to claim 2 or 3 wherein said port is one of a multiplicity of circumferentially spaced apertures formed in said casing.

6. A combination according to claim 2 wherein said casing is formed with a plurality of rows of circumferentially spaced apertures adapted to communicate with said inlet and outlet ducts.

7. A combination according to any one of the preceding claims wherein said tube is at least partly packed in a bellows-like configuration.

8. A combination according to any one of claims 1—6 wherein said tube is coiled in said casing.

9. A combination according to claim 1 or 2 wherein said fluid distribution body is constituted by a box and wherein said probe cartridge is constituted by a reel rotatably mounted in the box, there being furthermore provided means for rotating the reel, a probe outlet of the box constituting said probe holder opening and adapted to accommodate a probe adapter unit to which the ends of the probe are secured, fluid inlet and outlet ports of the box and box sealing means.

10. A medical probe system substantially as hereinbefore described with reference to and as shown in Figures 2 and 3, or Figures 4 and 5, or Figure 6, or Figure 7, or Figure 8, or Figures 9 and 10, or Figures 11 and 12 or Figure 13 of the accompanying drawings.

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Sheet 1

FIG1

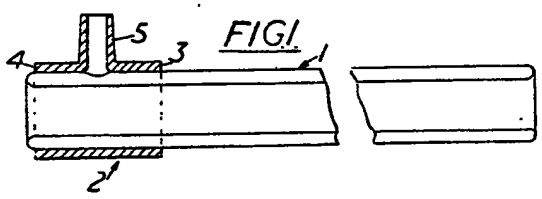


FIG5

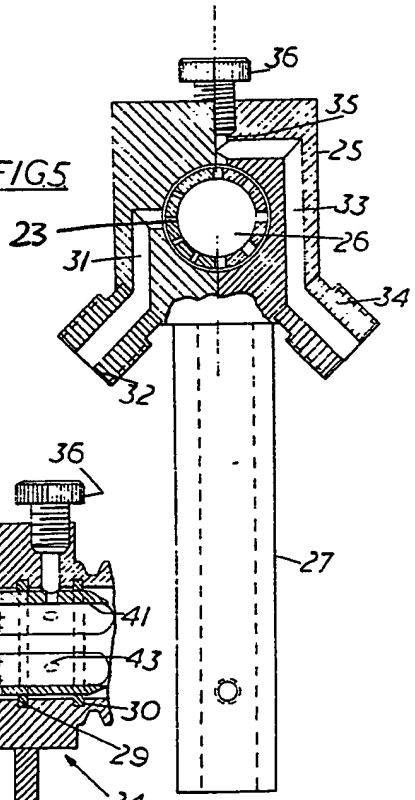
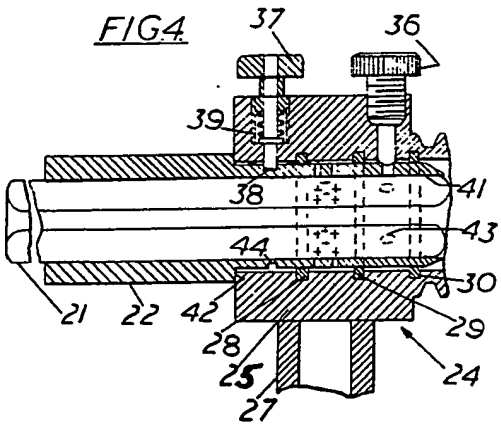


FIG4



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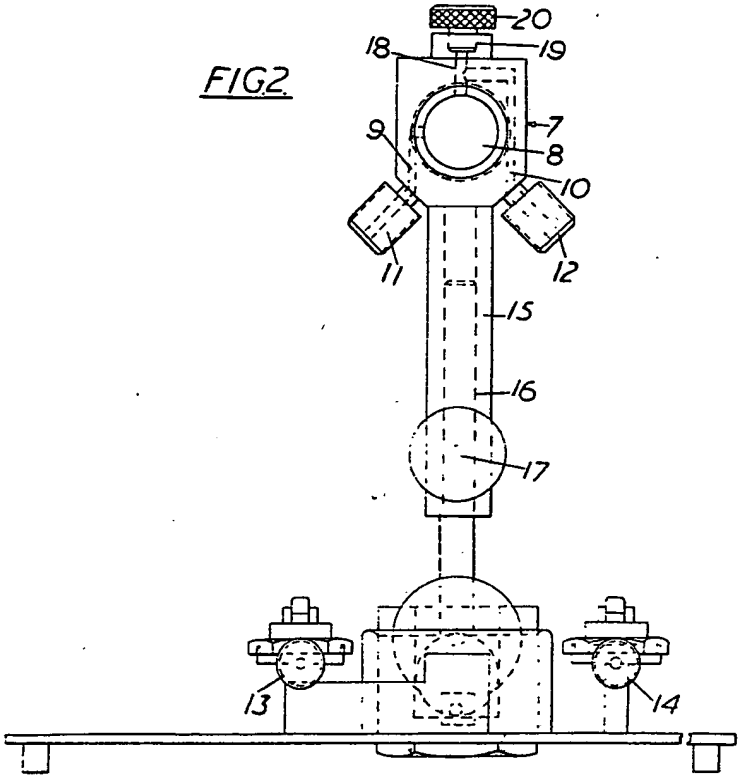
Sheet 2

FIG2.



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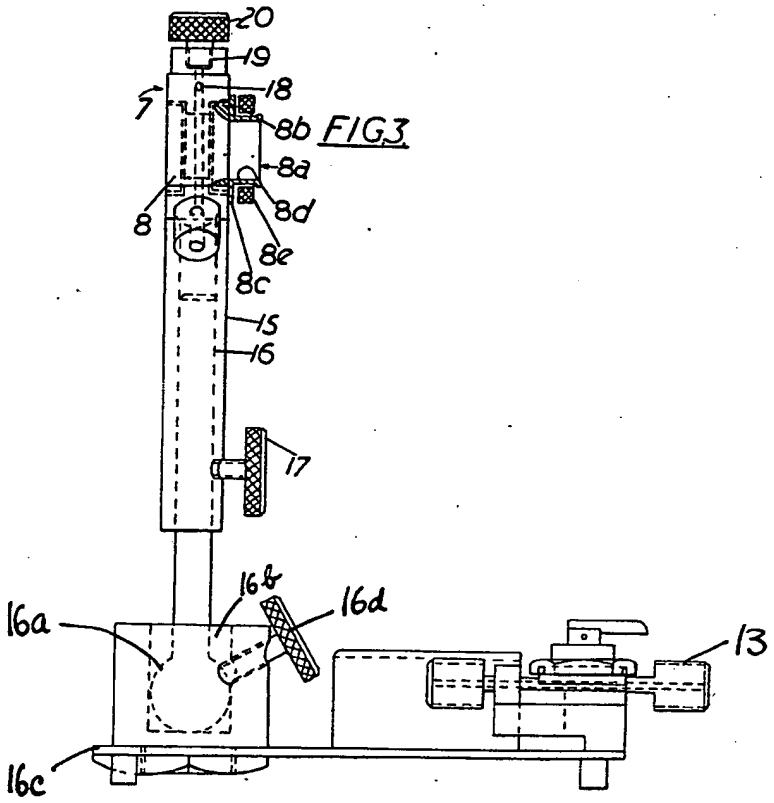

FIG3

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Sheet 4

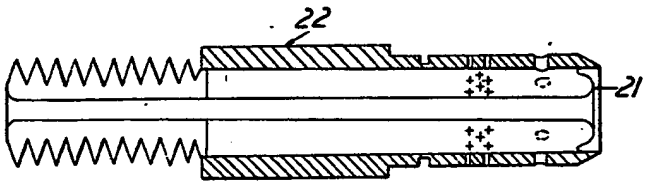


FIG6

FIG7

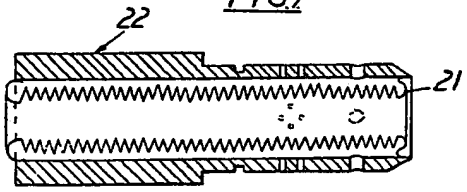
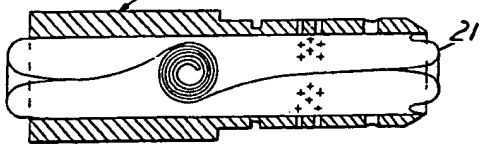


FIG8



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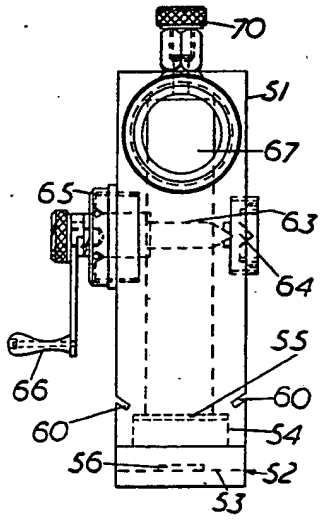
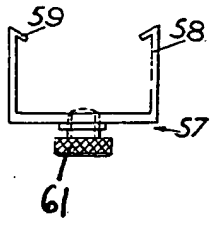
Sheet 5

FIG9





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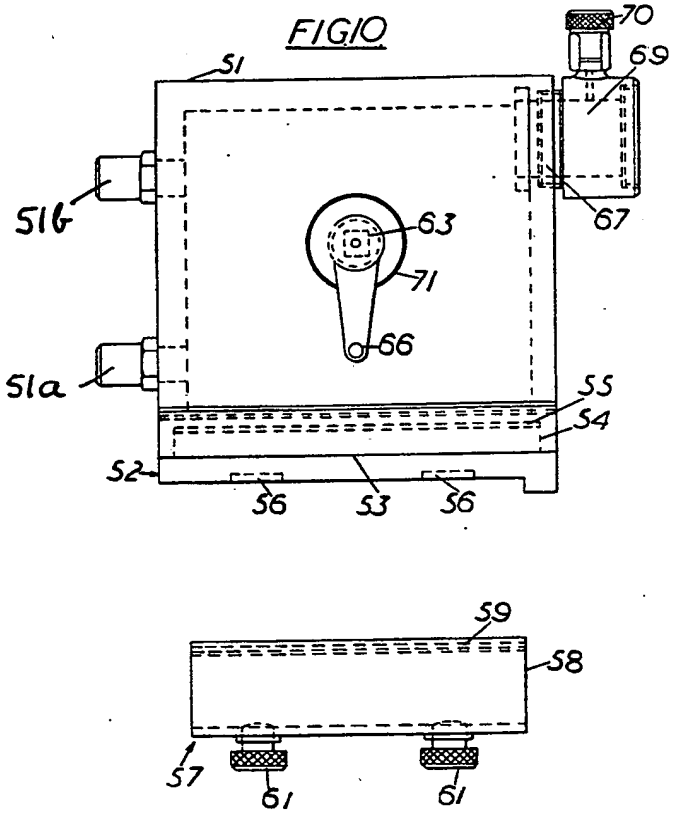
Sheet 6

FIG10



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Sheet 7

FIG11

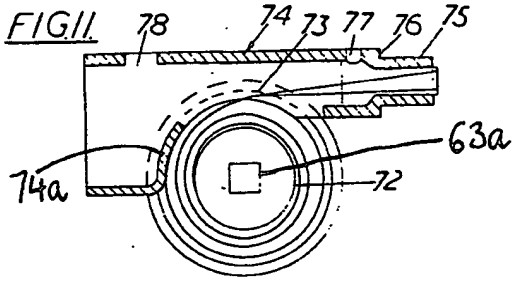

FIG12

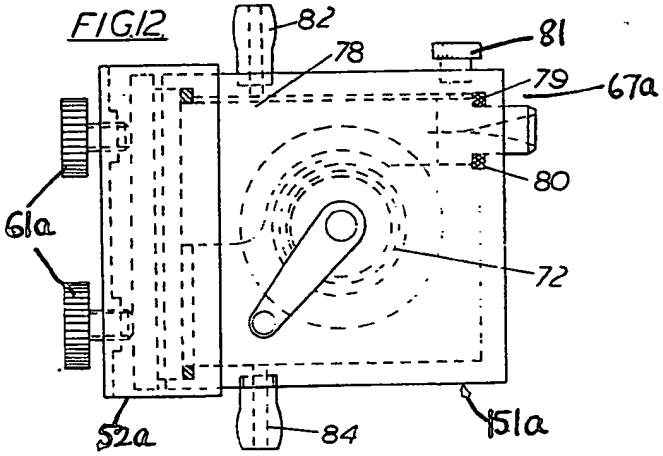

FIG13